Attorney Docket No.: Q101074

AMENDMENT UNDER 37 C.F.R. § 1.111

Application No.: 10/547,843

REMARKS

Upon entry of the claim amendments, Claims 1-2, 4-7, 10, 17 and 26 will be all the claims pending in the application.

Claims 1-2, 4, 6-7, 10 and 17 are amended.

Claims 3, 8-9, 11-16, 18-25, and 27-36 are canceled.

The specification and the Sequence Listing have been amended.

No new matter is added.

I. RESPONSE TO OBJECTION UNDER 37 C.F.R. § 1.75(c)

Referring to Section No. 2 at page 2 of the Office Action, Claims 3-4, 10, and 17 are objected to under 37 C.F.R. § 1.75(c) as being of improper dependent form.

In response, the recitations of "partial peptide" in Claims 10 and 17 have been deleted. Also, Claim 3 has been canceled, and Claim 4 has been rewritten as an independent claim.

Withdrawal of the present objection is requested.

II. RESPONSE TO REJECTION UNDER 35 U.S.C. § 101

Referring to Section No. 4 at page 3 of the Office Action, Claims 1-6 are rejected under 35 U.S.C. § 101.

In response, Claims 1-2 and 4-6 have been amended to be directed to "an isolated" protein or polynucleotide.

III. RESPONSE TO REJECTION UNDER 35 U.S.C. § 101

Referring to Section No. 5 at page 3 of the Office Action, Claims 1-10, 17, and 26 are rejected under 35 U.S.C. § 101.

Applicants respectfully traverse. The presently claimed subject matter is supported by a specific and substantial credible asserted utility for the following reasons.

As shown in Examples of the present specification, the presently claimed protein comprising the amino acid sequence of SEQ ID NO: 1 (hereinafter, "Cl") has a cell-death

Attorney Docket No.: Q101074

AMENDMENT UNDER 37 C.F.R. § 1.111

Application No.: 10/547,843

promoting activity (Example 4), and an inhibitory activity on secretion of A β 40 and A β 42 (Example 5).

A great number of reports show an important role of endoplasmic reticulum stress response in various neurodegenerative diseases including Alzheimer's disease. See, for example, J Neuropathol Exp Neurol.2006 Apr:65(4) 348-357, Biochim Biophys Acta.2001 May:31:1536(2-3):85-96, Cell.2001 105:891-902. Each of these references has been made of record in the present application by the accompanying IDS.

At the time the present application was filed, it was known that endoplasmic reticulum stress-inducible protein, Herp, enhances presenilin-mediated generation of amyloid β -protein (Sai et al., J Biol chem. 2002 Apr 12; 277(15): 12915-20). It was also known that Parkin, the gene responsible for AR-JP (autosomal recessive juvenile parkinsonism) and the expression of which is induced by endoplasmic reticulum stress, suppresses unfolded protein stress-induced cell death.

Thus, those skilled in the art would readily understand that an agent that promotes cell death and inhibits secretion of amyloid β -proteins can be used for treatment of neurodegenerative diseases such as Alzheimer's disease.

As indicated in the Examples of the present specification, the expression of C1 is enhanced by endoplasmic reticulum stress (Examples 1 and 2), and C1 promotes cell death and inhibits secretion of amyloid β -proteins (Examples 4 and 5). Thus, the present specification, in view of the common general knowledge as of the filing date of the present application, supports a specific and substantial credible asserted utility of C1 as a prophylactic/therapeutic agent for neurodegenerative diseases (for example, Alzheimer's disease).

Reconsideration and withdrawal of the present §101 rejection is requested.

IV. RESPONSE TO REJECTION UNDER 35 U.S.C. § 112

Referring to Section No. 7 at the bottom of page 6 of the Office Action, Claims 1-10, 17, and 26 are rejected under 35 U.S.C. § 112, first paragraph.

Applicants respectfully traverse.

Attorney Docket No.: Q101074

AMENDMENT UNDER 37 C.F.R. § 1.111

Application No.: 10/547,843

For the reasons stated at Section III above, the presently claimed subject matter has a specific and substantial credible asserted utility. Thus, those skilled in the art would know how to make and use the presently claimed subject matter.

Reconsideration and withdrawal of the present §112 rejection is requested.

V. RESPONSE TO REJECTION UNDER 35 U.S.C. § 112

Referring to Section No. 8 at page 7 of the Office Action, Claims 8-9 are rejected under 35 U.S.C. § 112, first paragraph.

Without acknowledging the merits of the present §112 rejection, and solely to expedite prosecution of the other claimed embodiments, Applicants have canceled Claims 8 and 9, thereby rendering moot the present §112 rejection. Applicants reserve the right to file a continuation application(s) directed to any and all canceled subject matter and any other patentable disclosed embodiments.

VI. RESPONSE TO REJECTION UNDER 35 U.S.C. § 112

Referring to Section No. 9 at pages 7-10 of the Office Action, Claims 1, 3-5, 7-10, 17, and 26 are rejected under 35 U.S.C. § 112, first paragraph.

In response, Applicants have amended the claims by deleting therefrom the recitation of "substantially the same."

Reconsideration and withdrawal of the present §112 rejection is requested.

VII. RESPONSE TO REJECTION UNDER 35 U.S.C. § 112

Referring to Section Nos. 11-13 at page 10 of the Office Action, Claims 9-10, 17, and 26 are rejected under 35 U.S.C. § 112, second paragraph.

In response, Applicants have amended the claims by deleting therefrom the recitation of "partial peptide."

Reconsideration and withdrawal of the present §112 rejection is requested.

Attorney Docket No.: Q101074 AMENDMENT UNDER 37 C.F.R. § 1.111

Application No.: 10/547,843

VIII. RESPONSE TO REJECTION UNDER 35 U.S.C. § 102

Referring to Section No. 15 at page 11 of the Office Action, Claims 3-5, 7-10, 17, and 26 are rejected under 35 U.S.C. § 102(b) as being anticipated by the Hillman document.

Applicants respectfully traverse.

Applicants have amended the claims by deleting therefrom the recitations of "substantially the same" and "partial peptide." Accordingly, the presently claimed subject matter is novel and unobvious over the applied art.

Reconsideration and withdrawal of the present §102 rejection is requested.

CONCLUSION IX.

Reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the examiner feels may be best resolved through a personal or telephone interview, the examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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